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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,465	08/19/2003	Dan M. Granoff	2300-1238.11 PP01238.115	4108
27476	7590	05/12/2005	EXAMINER	
Chiron Corporation Intellectual Property - R440 P.O. Box 8097 Emeryville, CA 94662-8097			DEVI, SARVAMANGALA J N	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 05/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/643,465

Applicant(s)

GRANOFF ET AL.

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11-14 ~~is/are~~ are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-14 ~~is/are~~ are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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## **RESPONSE TO APPLICANTS' AMENDMENT**

### **Applicants' Amendment**

- 1) Acknowledgment is made of Applicants' amendment filed 02/18/2005 in response to the non-final Office Action mailed 12/15/04. With this, Applicants have amended the specification.

### **Status of Claims**

- 2) Claims 11-14 have been amended via the amendment filed 02/18/05.  
Claims 11-14 are pending and are under examination.

### **Prior Citation of Title 35 Sections**

- 3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

### **Prior Citation of References**

- 4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

### **Objection(s) Withdrawn**

- 5) The objection to the specification made in paragraph 6(a) of the Office Action mailed 12/15/04 is withdrawn in light of Applicants' amendment to the specification.  
6) The objection to the specification made in paragraph 6(b) of the Office Action mailed 12/15/04 is withdrawn in light of Applicants' amendments to the specification.

### **Rejection(s) Moot**

- 7) The provisional rejection of claim 11 made in paragraph 8 of the Office Action mailed 12/15/04 under the judicially created doctrine of obviousness-type double patenting over claim 35 of the co-pending application SN 10/121,456, is moot in light of the cancellation of claim 35 in the co-pending application 10/121,456.

### **Rejection(s) Withdrawn**

- 8) The rejection of claim 11 made in paragraph 10(a) of the Office Action mailed 12/15/04 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants'

amendment to the claim.

9) The rejection of claim 11 made in paragraph 10(b) of the Office Action mailed 12/15/04 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn n light of Applicants' amendment to the claim.

10) The rejection of claim 11 made in paragraph 10(c) of the Office Action mailed 12/15/04 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn n light of Applicants' amendment to the claim.

11) The rejection of claim 11 made in paragraph 10(d) of the Office Action mailed 12/15/04 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn n light of Applicants' amendment to the claim.

12) The rejection of claim 11 made in paragraph 10(e) of the Office Action mailed 12/15/04 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn n light of Applicants' amendment to the claim.

13) The rejection of claims 12-14 made in paragraph 10(f) of the Office Action mailed 12/15/04 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn n light of Applicants' amendment to the claim.

14) The rejection of claim 11 made in paragraph 12 of the Office Action mailed 12/15/04 under 35 U.S.C § 102(b) as being anticipated by Jennings *et al.* (*J. Exp. Med.* 165: 1207-1211, 1987 - Applicants' IDS) as evidenced by Seid (US 6,638,513), is withdrawn n light of Applicants' amendment to the claim.

### **New Rejections Based on Amendments**

The new rejections set forth below are necessitated by Applicants' amendments to the claims.

#### **Rejection(s) under 35 U.S.C § 112, Second Paragraph**

15) Claims 11-14 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 11 is incorrect and/or inconsistent in the limitations: '*meningitides*' (see line

8) and '*meningitidis*' (see lines 26).

(b) Claims 12-14 are vague and confusing in the phrase: 'library of molecules comprises' a peptoid library, peptide library and a phage-display library respectively because it is not clear whether or not the 'peptide library', 'peptoid library' or 'phage-display' library is meant to a subgenus within the genus of 'library of molecules'? For clarity and for the purpose of distinctly claiming the subject matter, it is suggested that Applicants replace the limitation 'comprises' with the limitation --is--.

(c) Claims 12-14, which depend from claim 11, are also rejected as being vague and indefinite because of the vagueness or indefiniteness identified above in the base claim.

### **Rejection(s) under 35 U.S.C § 102**

16) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

17) Claim 11 is rejected under 35 U.S.C § 102(e)(2) as being anticipated by Jennings *et al.* (US 5,683,699, filed 12/14/1989 – Applicants' IDS) ('699).

The limitation 'a library of molecules' is interpreted in this rejection as 'a collection of molecules'.

Jennings *et al.* ('699) taught a method of providing a library of N-acyl group B meningococcal polysaccharide (GBMP) molecules, i.e., N-propyl, N-butyl, N-pentyl and N-hexyl and contacting with antibodies specific to an N-propionylated group B meningococcal capsular polysaccharide which antibodies did not cross-react with the native GBMP or N-acetylated GBMP (i.e., non-autoreactive antibodies) under the conditions of a precipitation test that allow immunological binding between the antibodies and the N-Pr-GBMP molecules to form the precipitates, i.e., complexes, separating the precipitates or complexes from non-bound molecules

by centrifugation, and identifying the specific N-acyl GBMP that did and that did not immunoreact with said antibodies (see section c in column 8 and 9; and Table 2). By disclosing that N-Pr-GBMP molecules mimic a unique bactericidal epitope on the surface of group B meningococci (see lines 50-54 in column 2), Jennings *et al.* ('699) taught that the N-Pr-GBMP molecules serve as mimics (i.e., molecular mimetics) of a unique epitope of serogroup B *Neisseria meningitidis*. That the prior art N-Pr-GBMP-specific antibodies specific to a unique epitope of serogroup B *Neisseria meningitidis* are non-autoreactive in that the antibodies do not elicit an autoimmune response is inherent from the teachings of Jennings *et al.* ('699) in light of what is well known in the art. For instance, Seid disclosed that antibodies specific to a unique epitope of serogroup B *Neisseria meningitidis* that reacts with N-Pr-GBMP-specific antibodies are non-cross reactive with host tissues and with the human neuroblastoma cell line CHP-134, i.e., non-autoreactive antibodies. See first full paragraph in column 5; claims; and paragraph bridging columns 11 and 12.

Claim 11 is anticipated by Jennings *et al.* ('699). Seid is not used as a secondary reference in combination with Jennings *et al.* ('699), but rather is used to show that every element of the claimed subject matter is disclosed by Jennings *et al.* ('699). See *In re Samour* 197 USPQ 1 (CCPA 1978).

### Remarks

18) Claims 11-14 stand rejected. Claims 12-14 contain allowable subject matter.

19) Applicants' amendments necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

20) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile

transmission. Papers should be transmitted via the PTO Fax Center which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of amendments, responses and/or papers is (703) 872-9306.

**21)** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**22)** Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.45 a.m to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

May, 2005

  
S. DEVI, PH.D.  
PRIMARY EXAMINER